

In the claims:

Please cancel non-elected claims 44, 46, 49, 51 and 56 without prejudice to applicants' right to pursue the subject matter thereof in a continuing application.

Please cancel pending claims 1-3, 6, 8, 14, 15, 18, 20, 21, 27, 28, 31, 32, 34, 38, 39, 42 and 43 without prejudice to applicants' right to pursue the subject matter thereof in a continuing application.

Please insert new claims 58-68 as follows:

- Sub C1*
58. (New) A method for predicting pregnancy outcome in a subject comprising the steps of:
- (a) (i) contacting a first portion of a sample from the subject with a first antibody which binds to the early pregnancy-associated molecular isoform of hCG that is recognized by the B152 antibody deposited with the American Type Culture Collection under Designation No. HB-12467;
  - (ii) contacting the sample resulting from (a)(i) with a second, labeled antibody capable of binding to the early pregnancy-associated molecular isoform of hCG simultaneously with the first antibody;
  - (iii) measuring the amount of any complex formed between the first and second antibodies and the early pregnancy-associated molecular isoform of hCG in the sample, so as to thereby determine the amount of the hCG isoform in the sample;
- B1*

- (b) (i) contacting a second portion of the sample from the subject with a third antibody which binds to intact non-nicked hCG;
- (ii) contacting the sample resulting from (b)(i) with a fourth, labeled antibody capable of binding to intact non-nicked hCG simultaneously with the third antibody;
- (iii) measuring the amount of complex formed between the third and fourth antibodies and the intact hCG in the sample, so as to thereby determine the amount of intact hCG in the sample, with the proviso that steps (a) and (b) can be performed in any order; and
- (c) determining the ratio of the early pregnancy-associated molecular isoform of hCG to intact hCG in the sample from the measurements performed in (a)(iii) and (b)(iii), wherein a ratio greater than 1 indicates a positive pregnancy outcome and a ratio less than 1 indicates a negative pregnancy outcome.

59. (New) The method of claim 58, wherein one of the antibodies in each of steps (a) and (b) is bound to a solid support.
60. (New) The method of claim 58, wherein the sample is a urine sample.
61. (New) The method of claim 60, wherein the urine sample is obtained from the subject within the first five weeks of pregnancy.

b1

Sub C2  
62. (New) A method for determining the amount of early pregnancy-associated molecular isoform of hCG present in a sample comprising the steps of:

- (i) contacting a sample from the subject with a first antibody which binds to the early pregnancy-associated molecular isoform of hCG that is recognized by the B152 antibody deposited with the American Type Culture Collection under Designation No. HB-12467;
- (ii) contacting the resulting sample with a second, labeled antibody capable of binding to the early pregnancy-associated molecular isoform of hCG simultaneously with the first antibody; and
- (iii) measuring the amount of complex formed between the first and second antibodies and the early pregnancy-associated molecular isoform of hCG in the sample, so as to thereby determine the amount of the hCG isoform in the sample.

63. (New) A diagnostic kit for predicting pregnancy outcome in a subject comprising:

- (a) a first antibody, bound to a solid support, which binds to the early pregnancy-associated molecular isoform of hCG that is recognized by the B152 antibody deposited with the American Type Culture Collection under Designation No. HB-12467;
  - (b) a second, labeled antibody which binds to the early pregnancy-associated molecular isoform
- B1

of hCG simultaneously with the antibody of  
(a);

(c) a third antibody, bound to a solid support,  
which binds to intact non-nicked hCG;

(d) a fourth, labeled antibody which binds to  
intact non-nicked hCG simultaneously with the  
antibody of (c); and

(e) reagents permitting binding between the  
antibodies and their respective antigens in a  
sample from the subject.

64. (New) The diagnostic kit of claim 63, wherein the  
second antibody is B207 deposited with the American  
Type Culture Collection under Designation No. PTA-  
1626.

65. (New) The diagnostic kit of claim 63, wherein the  
third antibody is B109 deposited with the American  
Type Culture Collection under Designation No. PTA-  
1624.

66. (New) The diagnostic kit of claim 63, wherein the  
fourth antibody is B108 deposited with the American  
Type Culture Collection under Designation No. PTA-  
1625.

*Sub C3*  
*B1*

~~67. (New) An antibody which binds to the early  
pregnancy-associated molecular isoform of hCG that  
is recognized by the B152 antibody deposited with  
the American Type Culture Collection under  
Designation No. HB-12467.~~

*B1  
cancel*

68. (New) The isolated early pregnancy-associated isoform of hCG recognized by the B152 antibody deposited with the American Type Culture Collection under Designation No. HB-12467.

REMARKS

Claims 1-3, 6, 8, 14, 15, 18, 20, 21, 27, 28, 31, 32, 34, 38, 39, 42 and 43 are pending. Claims 1-3, 6, 8, 14, 15, 18, 20, 21, 27, 28, 31, 32, 34, 38, 39, 42 and 43 have been canceled without prejudice. New claims 58-68 have been added to more particularly claim what applicants regard as the invention. New claim 58 corresponds to canceled claims 2 (labeled antibody), 6, 18, 20 and 21 (use of anti-hCG antibodies). New claim 59 corresponds to canceled claim 14. Support for new claims 60 and 61 may be found at page 38 of the specification in Table 4 and in Figures 4 and 5. New claim 62 corresponds to canceled claims 2, 6 and 27. New claims 63 and 64 correspond to canceled claim 31. New claims 65 and 66 correspond to canceled claim 32, and new claim 67 corresponds to canceled claim 38. New claim 68 corresponds to canceled claim 43. Applicants submit that these amendments raise no issue of new matter. Thus, claims 58-68 are now pending and under examination.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the May 14, 2002 Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.